Monitoring of Side Effects Scale (MOSES)

This section presents the MOSES, the MOSES examination, the various levels of side effect inquiry, and the relationship of MOSES to the levels of inquiry. The MOSES is presented in Figure 3-1. A clean copy should accompany this manual.

BASIC PARADIGM

It is important to again emphasize that MOSES is designed to detect clinical manifestations (CM) which **may** represent a side effect. The presence of these clinical manifestations does not necessarily mean a side effect is present. MOSES does not diagnosis a side effect. It only provides information about the client similar to the way laboratory tests provide information about physiological levels such as albumin, creatinine, white blood cells, glucose, etc. The information is analyzed by the prescriber to determine if a side effect is present.

The basic paradigm for the use of the MOSES may be conceptualized by the following four steps:

Step 1: "Detect the Problem." An assessment with MOSES is made to determine if clinical manifestations are present and, if so, at what level. In performing this step, it is important to **"score what you see."** If there is an obvious, known, or suspected reason for the CM (e.g., drowsiness due to narcolepsy), score the item and enter an explanation in the Rater Comments area.

Step 2: "Determine if a Side Effect Is Present." The MOSES is reviewed and evaluated by the prescriber within the context of the client and related variables such as medications, underlying conditions, medication changes, etc. An important aspect of this step is to determine if further assessment or data through more specialized scales or measurement, lab tests, or consultation is necessary.

Step 3: "Decide What To Do." If the prescriber concludes a side effect is present, a risk:benefit analysis is undertaken, a decision as to any action or change determined, and a plan to implement and determine the effect of the change documented. If the side effect is minimal to mild and no action is deemed necessary or if the continued treatment of a previously treatment-resistant condition is deemed essential despite the side effect, ongoing information about the status of the side effect is provided by subsequent MOSES assessments. An important aspect of this step is to inform the patient or guardian about the side effect and involve the patient or guardian in the decision to the degree possible. While perhaps more informational and perfunctory for minor side effects or minor medication adjustments, this is especially important for more serious side effects or when more difficult risk:benefit decisions must be made.

Step 4: "Discern if It Helps." The effect of the decision is evaluated. If the decision does not lead to improvement, any of the first three steps are revisited. Status or outcome is provided by subsequent MOSES assessments.

Four MOSES Situations

In reality, the following four basic situations will likely occur as a result of the MOSES:

- **No clinical manifestations are present.** Evaluation, decisions, and documentation will be straightforward and non-time consuming.

- **Clinical manifestations are present, but it is clear they do not represent a side effect.** Evaluation and decisions will be straightforward *and non-time consuming. Please note it is* likely the first such MOSES for an individual will require extra time to document the cause or reason for the clinical manifestations. However, subsequent MOSES documentation will be non-time consuming because the explanation is simply cross-referenced.

- **Clinical manifestations are present, and it is clear they represent a side effect.** Evaluation, decisions, and documentation will be straightforward and non-time consuming. One exception is if a more pronounced side effect is present, but other options for a previously treatment resistant condition are not available. Documentation time, at least for the first such MOSES, would be expected to be time-consuming.

- **Clinical manifestations are present, but it is not clear they represent a side effect** (that is, more data is needed). Evaluation, decisions, and documentation will be more complex in this situation. A special team meeting to plan or obtain consultation, gather more data, or implement actions to test a hypothesis may be needed. An exception may occur if clinical manifestations are minimal, do not pose a threat to the client, and no immediate action is necessary. Subsequent MOSES checks will indicate if clinical manifestations intensify and require more specific inquiry and action.

MOSES

Development

The MOSES was developed in 1984 and published in 1988 (Kalachnik, 1988). It was adapted for use within the State of Minnesota system in 1987 by a task force of psychiatrists, physicians, pharmacists, and nurses. This occurred as a result of a class action lawsuit filed in United States District Court and the resulting Consent Decree agreement. The author served as Chair of this task force, and professors from the University of Minnesota Department of Psychiatry served as advisors. Over the years, MOSES has been expanded and revised several times from its original version based upon user feedback (Kalachnik, 1999). In addition to the State of South Carolina DDSN system, the State of Iowa system has implemented the MOSES as have several facilities in the State of Virginia, and at least one facility the State of North Carolina. Recently, the State of Illinois has started the process of implementation.

Face Validity

To insure MOSES face validity (i.e., the items indeed represent actual clinical manifestations of side effects), the following references were used: *American Hospital Formulary Service, Facts and Comparisons, United States Pharmacopeia,* review articles in professional journals, and side effects scales available at the time. The Minnesota task force and advisors also reviewed the items and made several additions and revisions.

MOSES was specifically researched and designed for psychopharmacologic medication and antiepileptic medication. Other drug classes (e.g., corticosteroids) were not reviewed or included.

Concepts Incorporated by MOSES

The MOSES is based upon several concepts. Foremost was the fact that MOSES was designed for applied clinical use.

- **Signs and symptoms are listed in layperson's language.** There were several reasons for this. First, MOSES was intended for use by a wide variety of people, not all of whom were likely to know the specific signs or symptoms for a side effect such as dystonia. This was especially important for the emerging group home area where not all checks were likely to be conducted by registered nurses. Second, health care professionals on the Minnesota task force indicated that when using a scale, they were more interested in "a list of specific signs and symptoms to check for" instead of "a side effect name." These professionals noted they could cognitively synthesize clinical manifestations and reach a conclusion as to what side effect was present based upon what drug(s) was prescribed. As one task force member observed, "Let's base the system on the assumption that 98% of health care professionals are competent instead of incompetent."

- **Signs and symptoms are listed by body area.** Task force physicians and nurses indicated a design similar to a typical physical examination would keep the procedure consistent with a familiar ongoing process.

- **Some items are bold and some are not.** Not all clients are verbal. Therefore, and for examiner convenience, a differentiation was made between items which could be observed during the examination **(bold items; e.g., Item 40: Tremor)** and items which usually must be verbally related by the individual (non-bold items; e.g., Item 7: ear ringing). Items which are observable at times other then during the examination (e.g., Items 21-22: increased or decreased appetite) were made non-bold because the examiner must talk with staff or review charts for non-verbal individuals. Some non-bold items may occasionally be able to determined for non-verbals individuals (e.g., a non-visually impaired person who continually bumps into things or seems to walk using the wall for guidance may indicate blurred vision from a medication with anticholinergic properties). Non-bold items are usually able to be determined during the examination for verbal individuals although the veracity of a report or non-report for some individuals may need to be cross-checked with

family or staff.

- **Some items do not have the scoring levels listed next to them.** Field testing indicated people did not like to repeatedly circle "NA" for items which were consistently "not assessable" for non-verbal clients. This does not mean that the item cannot be ascertained for all non-verbal clients, and it does not mean the item cannot be ascertained for verbal clients. Because the items are important and must not be overlooked, specific instructions are provided on the form to remind the rater to consider the item, inquire about the item if the client is verbal, and circle the item and provide a score if it is present.

- **A rater comment section is provided.** Field testing indicated people detected a number of clinical manifestations which were part of an underlying psychiatric, medical, or behavioral condition and not side effects. Great concern was expressed that there was no convenient way to explain this so others would not think side effects were present and ignored. Therefore, a rater comments section was added to the back of the MOSES because clinical manifestations are scored no matter what their cause. For example, a client is prescribed lithium and displays "Item 28: increased thirst" at a moderate level. The item is scored. However, the client also has a long-standing psychiatric/behavioral diagnosis of polydipsia. This is explained in the comments section in relation to the item. While increased thirst could be a side effect of lithium, the clinical manifestation in this situation would probably not be a side effect of lithium.

Three MOSES Subscales

The MOSES contains three subscales which may be useful. Please note that although the dyskinesia subscale items are also present on the DISCUS, they were included on the MOSES because several other medications such as tricyclic antidepressants and stimulants, while not causing tardive dyskinesia, may cause acute dyskinesias. The three subscales are:

Anticholinergic

Item 6: blurred/double vision
Item 10: dry mouth
Item 23: constipation
Item 49: color: flushing/warm to touch
Item 67: urinary retention
Item 68: urinary: decreased
Item 73: confusion

Extrapyramidal System (EPS)

Item 1: blink rate: decreased
Item 3: eyes rolled up
Item 4: face: no expression/masked
Item 9: drooling/pooling
Item 31: arm swing: decreased
Item 32: contortions/neck-back arching
Item 34: gait: shuffling
Item 36: movement: slowed/lack of
Item 37: pill rolling
Item 38: restlessness/pacing/can't sit still
Item 39: rigidity/complaints of muscle pain or aches
Item 40: tremor/shakiness
Item 41: complaints of jitteriness/jumpiness/nervousness

Dyskinesia

Item 5: tics/grimace
Item 12: mouth/tongue movement
Item 35: limb jerking/writhing

The subscales may serve two functions. First, the points for the items in a subscale may be totaled. This may provide a useful method to track the effect of an intervention if the side effect is determined to be present. Second, the subscales may provide direction as to what the clinical manifestations represent. For example, the presence of dry mouth, constipation, and decreased urination would strongly suggest the presence of an anticholinergic side effect. Please note, however, that any individual item does not inevitably represent the side effect category and may instead represent a side effect in and of itself or another side effect. For example, (a) Item 38 (restlessness/pacing/can't sit still) could be a manifestation of discomfort due to abdominal pain or a state-exacerbated behavioral side effect, (b) Item 73 (confusion) may be related to histamine-related sedation, and (c) Item 40 (tremor) may be related to blockade of norepinephrine uptake at nerve endings instead of EPSE pseudoparkinsonism and dopamine receptor blockade. It is also possible other MOSES items may be related to the subscale side effect. For example, some references suggest Item 13 (speech: slurred/difficult/slow) may occur in some cases of anticholinergic side effects or EPSE.

MOSES Total Score and Body Area Scores

The MOSES does not include a total score box or body area subtotal score boxes at this time for three reasons.

First, as recommended by task force physicians and nurses, signs and symptoms were placed in the body areas listed in order to approximate the organization of a typical physical examination. As a result, items which may represent the same side effect may be in different body areas. For example, as reviewed under the MOSES subscales, the pseudoparkinsonism sign of decreased blink rate (Item 1) is listed in Ears/Eyes/Head while tremor/shakiness (Item 40) is listed in Muscuoskeletal/Neurological. Some common serotonin reuptake-related side effects are listed in both the Gastrointestinal (e.g., Item 20, 21, 24, etc.) and Urinary/Genital (e.g., Item 62, 65, etc.) areas. Body area subtotals, therefor, were not necessarily reflective of such situations. Second, task force members and field-testing personnel considered the use of body area scores and total score would not do justice to proper analysis of side effects for an individual. Each MOSES item was considered important in and of itself because clinical manifestations may vary from patient to patient and situation to situation. And third, the average MOSES total score, body area subtotal scores, and standard deviations have not been formally determined. As a result, a meaningful psychometrically derived "indicator score" and "change score" was not able to be provided. This is a current weakness of the scale and efforts are being made in this direction.

However, much to the author's own surprise, he has found himself beginning an analysis with the MOSES total score, body area subtotal scores, the three subscale scores, and any change from the last MOSES before moving on to the individual items. One South Carolina facility, as a result of their pilot project and feedback from the prescriber involved, decided to: (1) write in the MOSES total score for Items 1-83 in the "Other Area" and (2) write each body area's subtotal score next to the heading for that section. As long as the nurse and prescriber remain alert to individual item changes, there is nothing wrong with this procedure, and it may be helpful to others despite the lack of scoring boxes and formal scoring psychometrics.

A prescriber at another South Carolina pilot facility complimented the MOSES and, when asked if there was anything he/she would like to see replied, "I would like to be able to compare MOSES scores across ratings over time to look at trends." While this is not possible at this time due to inability to obtain personnel to enter all the data from each MOSES on a computer, the following procedure may help in some situations: (1) enter the total score and body areas scores on the MOSES, (2) place a "do not remove" on the first MOSES done so it remains in the chart where MOSES forms are stored, and then, as time goes on, (3) compare the **current** MOSES total score (and body area scores) to the **last** MOSES **and** to the **baseline** "do not remove"[5] MOSES.

Suggestion for Item 27

One South Carolina pilot facility nurse and physician reported that Item 27 (taste abnormality: metallic, etc.) was conceptually difficult for individuals with mild to moderate mental retardation. One suggestion was to use the term "funny taste" as part of the examination when asking about this item. Another suggestion was to: (1) give a small taste of orange juice or pudding, and then (2) give a small taste of hydrogen peroxide and ask, "Does your mouth ever taste funny like this between meals?"

Yellow Highlighter Method

Comments by South Carolina pilot units confirmed that MOSES sensitivity was high and MOSES specificity was low.[6] In other words, MOSES correctly

---

[5] This "baseline"assessment is unlikely to be "drug-free." The technical definition of a baseline is accepting the conditions which are in effect at the time. Subsequent data and changes are compared to this.

[6] Sensitivity is the percent of people with a condition correctly identified by the procedure. If 100 people have side effects and a scale correctly identifies 95 (by detecting the clinical manifestations of the side effects), the scale is said to have 95% sensitivity. Specificity (or selectivity), on the other hand, is the percent of people without the condition correctly identified by the procedure. If 100 people do not have side effects and a scale correctly identifies 40 as not having side effects, the scale is said to have 40% specificity. "False negatives" potentially occur if sensitivity is less than 100%; that is, the person really has side effects and is missed. "False positives" potentially occur if specificity is less than 100%; that is, the person does not really have side effects although clinical manifestations are detected. In a perfect world, there would be 100% selectivity and 100% specificity. In reality, if a scale can achieve 80% selectivity and 80% specificity, it is considered excellent. Some systems like the FAA must have 99.99999999...% sensitivity for airline safety. The by-product of approximating 100% sensitivity is low specificity and more "false positives" such as flight cancellations, re-routing, weather delays, mechanical delays, and holding patterns to insure safety. Side effects monitoring errs on the side of high selectivity in order not to miss side effects because patient welfare are at stake.

identifies and brings to the presciber's attention people with clinical manifestations which are side effects, but, in throwing out this detection "net," MOSES "pulls in" many people with clinical manifestations from other conditions which are not side effects. While this is accepted as necessary ("better to check it and be wrong than to miss it and have something serious happen") and is expected with individuals with MRDD where a myriad of other conditions exist, it can, nonetheless, create time and logistical problems for the prescriber and nurse, especially when the MOSES process is to "score what you see" (even if the cause if known) and explain it in the comments section. As one physician phrased it, "At a review where I have to go through a number of assessments, if there is a case where a lot of clinical manifestations are already present and scored from other underlying conditions, I don't know which items to attend to and ask the nurse questions about. Also, if an item is already scored at a 4 (severe) due to another condition and it gets worse, how do I know when to attend to it?"

The following procedure may be helpful: **the nurse uses a yellow highlighter to indicate for the physician which MOSES items scored are of concern.** In addition to obvious verbal communication and discussion, this allows the nurse to efficiently alert the prescriber to: (1) an item scored high and previously explained, but which has subsequently become "different" or "problematic" due to a medication change and possible side effects, and (2) relevant items in terms of review for possible side effects when numerous items are scored due to manifestations from other conditions. Combined with saving certain MOSES assessments ("do not remove" from the chart) so as to save time by cross-referencing previous explanatory notes, the yellow-highlighter method should eliminate much of the real-life consequences of a system with high sensitivity and low specificity; namely, the extra time required when false positives occur. Three of the five South Carolina facilities incorporated the yellow highlighter procedure into their formal logistical procedure while the other two left such use up to the individual nurse and physician involved.

Current Psychopharmacologic and Antiepileptic Drug Regimen

The MOSES contains a box to list the psychopharmacologic medication, antiepileptic drugs, and "other relevant drugs such as those to treat side effects" prescribed at the time of the check. The intent of this was not to list the entire medication regimen consisting of topicals, daily vitamins, etc. Figure 3-2 presents a list of medications sometimes used to treat extrapyramidal side effects (EPSE) of antipsychotic medication, particularly non-atypical antipsychotic medication. These or other relevant medications do not require a MOSES unless prescribed for psychopharmacologic purposes (propranolol for intermittent explosive disorder and diphenhydramine for the short-term treatment of sleep problems are the likely exceptions in Figure 3-2).

It is important to remember that although all medications in the drug regimen do not have to be listed, the other medications may have side effects of their own (or possible drug interactions). These may need to be considered if clinical manifestations are detected. For example, beta-blockers prescribed for hypertension may sometimes cause depression, psychosis, or personality changes. The presence of MOSES Item 72 (agitation), Item 73 (confusion), Item 74 (crying/feelings of sadness), Item 76 (irritability), or Item 81 (peceptual: hallucinations/delusions) would prompt review to determine if a beta-blocker was recently started or the dose increased.

This section lists total daily dose instead of the dosing schedule for two reasons. First, it is usually easier to analyze changes and make comparisons in terms of total daily dose. Second, different doses may be prescribed at different times of the day. Listing these would have required space better used in the examiner comments section where pilot nurses indicated extra space was needed. For those outside of the medical or nursing professions, Figure 3-3 presents a list of dosing schedules which may be helpful in translating dose schedules to total daily dose. If a decanoate injection is encountered (e.g., haloperidol decanoate or fluphenazine decanoate), the "mg/day" should be crossed out and the dose and injection schedule entered (e.g., "Prolixin 50 mg every 21 days").

MOSES EXAMINATION

MOSES pilot nurses (all RNs) reported that the MOSES examination averaged about 15 minutes with a range between 10 and 20 minutes. The time required depended on several variables. These variables included: (1) whether the MOSES was conducted during the regular quarterly nursing review (shorter time because it was combined other nursing activity), (2) whether the DISCUS was done at the same time as the MOSES (longer time if conducting the DISCUS at another time was not factored in), (3) the extent to which staff interview or chart review was required (longer time), (4) whether substantial documentation was required to explain clinical manifestations which

were clearly not side effects (first MOSES longer time but subsequent MOSES shorter time), and (5) experience with the MOSES (longer for the first 5 to 10 examinations but subsequent shorter time).

In terms of training, one pilot RN observed that she trained a LPN working for her to do the MOSES to a high standard of reliability. This took about 5 examinations each of which took about one hour because the examination was done together and every item discussed. The RN reported that the MOSES went much faster after this and that she was completely comfortable with turning over half of the scheduled MOSES examinations to the LPN.

Some Reminders

- **Provide a courteous explanation of the examination.** It is important to explain the purpose and steps of the examination to the client before starting. Let the client know that if he or she is uncomfortable with any step it will be skipped. If the client is non-verbal, remain vigilant for behavioral signs of discomfort. The tone of your voice and an explanation will go a long way toward reassuring the client, even if the full meaning of your explanation is not understood.

- **Never force an exam step.** Skip any step the client resists or which causes discomfort or embarrassment. Often, if the step is skipped and agitation avoided, it is possible to conduct the rest of the examination. If a client does not want to do a step, remember he or she was given the option of skipping the step. Just say, "thanks for telling me" and move on to the next step.

- Some individuals cannot or will not perform the examination steps. **If there is little or no cooperation or ability, simply observe and interact as you are able.** Do not attempt to achieve the impossible. It is normal to have a number of "not assessable" (NA) items in such a situation.

- **Model examination steps.** An extremely useful procedure is to model as many of the steps as possible. Many clients will "imitate" your model.

- **Conduct the examination in a quiet private area which respects the individual's dignity.** If this is not possible due to non-cooperation, insure that the area is as quiet and as free of people and distractions as possible.

- **Associate the examination with positive events.** For example, have a "reinforcer tray" of soda, coffee, or some edible such as fruit or crackers. If cigarettes are allowed and the client enjoys this, include these on the reinforcer tray. Some facilities use a point privilege system and provide extra points for examination cooperation. Inform the client that you appreciate their help and that after the examination is over, they may have their choice of an item(s) (or receive points). Even if the examination is observational, but is a step in the right direction for the client, provide the items. Slowly, over time, the examination will be viewed as a positive activity and, in many cases, cooperation will increase.

MOSES Examination Steps

The MOSES examination is not meant to replace other professional nursing assessment skills or procedures. Rather, the examination is offered as a possible method to incorporate or use. Even if the entire examination procedure is not incorporated, there may be several steps which are valuable and can be added to an existing procedure.

1. **Global.** Ask the client to sit in a chair. Make a general survey of the client's apparent state of health, signs of distress, skin color, stature and habitus, weight, posture, motor activity, facial expression, manner, mood, state of awareness, and speech.

2. **Skin.** Inspect and palpate the hands, forearms, and face.

3. **Skin.** Lift a fold of skin and note the ease with which it is moved (mobility) and the speed with which it returns to place (turgor).

4. **Head.** Inspect the hair, scalp, and face. If verbal ask:

    - Are you ever bothered by headaches? How often? Is it more or about the same?

5. **Head.** Inspect the eyebrows, eyelids, scleras, conjunctiva, and ears. Ask the client to look up as you depress the lower lid of each eye with your thumb, exposing the sclera and conjunctiva. If verbal, ask:

    - Are you ever troubled by you vision? What is this like? Double? Etc.

- Do you hear unusual sounds in your ears?
- Is any of this more often or is it about the same?

6. **Head.** Ask the client to follow your finger as you sweep through six motions:

   - To the client's right
   - Upward, to the right of midline
   - Then straight down
   - To the client's left
   - Upward, to the left of midline
   - From there, straight down.

7. **Head.** Ask the client to open his or her mouth. Ask the client to stick out his or her tongue. Ask the client to close his or her mouth. If verbal, ask:

   - Are you bothered by a dryness in your mouth?
   - Do you have a stuffy nose?

8. **Head.** Ask the client to extend the neck slightly and to swallow. Alternatively, ask the client to drink some water from a glass.

9. **Hands and Legs.** Ask the client to take off their shoes and socks. If verbal, ask:

   - Do you ever have a tingling or numbness in your hands or arms?
   - Do you ever have a tingling or numbness in your feet or legs?

10. **Hands and Legs.** Palpate over the dorsum of the foot and over the shin by pressing firmly with the thumb for at least five seconds.

11. **Hands and Legs.** Ask the client to extend and spread the fingers of both hands. Ask the client to make a fist.

12. **Chest.** If possible and comfortable, ask the client to take off their shirt.

13. **Chest.** Ask the client to touch his or her chin to the chest. Ask the client to stretch the neck backward.

14. **Chest.** Ask the client to press his or her hand against the hips.

15. **Chest.** Gently compress each nipple between your thumb and index finger (note: to check for discharge). Explain step to client so they are not alarmed. Caution: skip if embarrassing to the client or if possible misinterpretation exists (e.g., inappropriate sexual advancement)

16. **Abdominal.** Ask the client to lie down. Using the pads of your fingertips with your fingers together, gently palpate all four quadrants of the abdomen using a light, gentle dipping motion. If the client is verbal, ask:

    - Are you troubled by nausea or vomiting
    - How are your bowel movements? Constipated? Diarrhea?
    - Do you have a lot of gas?
    - How is your appetite?
    - Do you have any strange tastes in your mouth?
    - Are you often thirsty?

17. **Neurological.** Ask the client to stand with arms at sides. If verbal, ask:

    - Do you have times where you feel faint? Dizzy?

18. **Neurological.** Ask the client to walk across the room. Also observe as client turns to change direction.

19. **Neurological.** Ask the client to extend his or her arms out in front with palms down. If verbal, ask:

    - Do you feel jumpy? (Observe for restlessness also)

20. **Neurological.** Grasp the client's upper arm with your left hand while grasping the client's lower arm with your right hand. Gently flex and extend the forearm several times. Repeat general procedure for shoulder and wrist. Turn head to one shoulder.

21. **Urinary/Genital.** Inquire if verbal.

22. **Psychological.** Document the observations you have made throughout the course of the examination (drowsiness, agitation, concentration, disjointed speech, etc.).

Systematic Inquiry for Verbal Clients

There are many individuals able to communicate the exact nature of side effects if prompted by the right question or inquiry. Figure 3-4 presents items adapted from the Systematic Assessment For Treatment Emergent Effects (SAFTEE) (Levine and Schooler,

1986).

For clinical use, the exact phrasing of an inquiry may be adapted by the examiner. The inquiries may also be useful for interviewing parents or staff who may spend a considerable amount of time with an individual. It should be noted that this is not a complete compendium of all possible inquiry techniques.

THREE ASSESSMENT LEVELS

Other then methods such as lab work or EEGs, it is important to understand that MOSES is but one of three possible assessment levels. These are referred to as the primary (1^0), secondary (2^0), and tertiary (3^0) level. Because levels become progressively more labor intensive, secondary and tertiary levels are usually reserved for confusing situations or cases requiring greater empirical tracking.

The 1^0 Level

The primary level consists of the MOSES assessment. The term "primary" is used because it is the starting point for side effects monitoring. Because MOSES is a general side effects scale, it does not provide precise or elaborate data about an item such as "decreased appetite" (i.e., **exactly** how much a client is or is not eating). MOSES does exactly what a general side effects scale is designed to do: provide a standardized checklist to check for clinical manifestations (CM) which alert the clinician to review the situation and, if necessary, obtain further data.

The 2^0 Level

The secondary level consists of a variety of side effect specific scales. The secondary level usually occurs in the following situations. The secondary level usually is terminated once the issue is resolved.

- MOSES detects a CM and more information is needed for differential diagnosis. For example, several movements are detected. An extrapyramidal side effects (EPSE) scale is used to better assess for dystonia, pseudoparkinsonism, or akathisia, especially in terms of meeting any available psychometric "indicator" scores.

- A side effect needs to be empirically tracked for a period of time with a scale containing more specific or extensive items for that side effect. For example, akathisia is detected and drug adjustments are likely. An akathisia scale is used to obtain data before and after the change in order to better and more formally evaluate the effect of the change.

The 3^0 Level

The tertiary level consists of measurement methods from behavioral psychology. These include frequency count, duration recording, time sample, interval recording, and behavioral rating scales. At the tertiary level, a specific side effect is defined and measured for a short period of time using these methods. In such a situation, a psychologist, behavior analyst, or similar person should be consulted to assist in designing the data collection system and relevant comparison variable(s) or value(s).

For example, Item 9 drooling is detected on the MOSES and confirmed as the critical sign of an extrapyramidal side effect (pseudoparkinsonism). Discussion with staff indicates the client's pillow is wet in the morning, and a medication modification is considered. The MOSES drooling item is considered too global, and an EPSE scale does not specifically address drooling in terms of the pillow aspect. A one week frequency count with an intensity measure for "morning pillow wetness" is designed implemented. Staff are asked to indicate if the pillow is wet (yes or no). If the answer is yes, staff are asked to indicate the level ranging from 1 (minimal) to 4 (severe). Each of these levels is described with some "anchor definitions" (e.g. minimal= small spot or one or two drops). Two weeks after the therapeutic change, staff are asked to repeat the process for one week. Composite data such as the number of drooling days per week, the total points for the week, or the average intensity per day (total points divided by the number of days) are possible to compare to evaluate the effect of the change.

Another example is eating. Item 21 (decreased appetite) is detected on the MOSES and more specific data is needed. A grid is constructed which lists (a) breakfast, lunch, and supper across the top, and (b) the seven days of the week down the side. Staff are asked to enter one of the following codes after each meal for one week: 0 = did not eat, 1= ate a little, 2 = ate about half the meal, 3 = ate most of the meal, 4 = ate entire meal, and 5 = ate entire meal and still hungry. Two weeks after the therapeutic change, staff are asked to repeat the process for one week. Composite data such as total meal points, the average rating for all meals (total points divided by total number of meals), the average rating for each meal (total points for that one meal divided by the number of that meal), or the percent of meals above a certain level (number of meals at 3 or above divided by the total number of

meals) are possible to compare. Actual weight over time, of course, can also be compared, but decreased appetite may not lead to decreased weight outside of the normal range for a period of time.

SUMMARY

The purpose of this section has been to review the MOSES and its development, examination, role within the side effects monitoring paradigm, and relationship (at the primary level) to more specific data at the secondary and tertiary levels. It is likely most MOSES situations will be straightforward. That is, it will be obvious whether clinical manifestations detected do or do not represent side effects. In a larger sense, though, and perhaps only in relation to less straightforward situations or those previously straightforward situations in which problems continue despite efforts, it is hoped the MOSES can provide "indicators" and be a springboard to look into a situation in more detail at the tertiary level, especially in regard to behavioral side effects. The step from someone observing "do you *think it is possible that...?*" to (1) *confirming with* professionals or the literature that the "that..." is possible to (2) the gathering of the team to work together to form a plan which respects and incorporates professional knowledge and staff insights to collecting specific data both before and after the intervention for purposes of evaluating whether the "that..." improved as a result of the intervention is a large one. However, seeing a client's life improve, sometimes dramatically, as a result of applying what is essentially the empirical scientific process to side effects monitoring, is an uplifting outcome.

[Excerpt from pp. 33-41 from Kalachnik, J.E., (2001). Standardized Monitoring for Psychopharmacologic Medication Side Effects. Manual for the Monitoring of Side Effects Scale (MOSES). University of South Carolina, School of Medicine, Department of Pediatrics, Center for Disability Resources, Columbia, SC and the South Carolina Department of Disabilities and Special Needs, Columbia SC.]